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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,027	02/28/2002	Domonkos Horvath	10642.9USWO	3517
23552	7590	08/05/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			O CONNOR, CARY E	
		ART UNIT	PAPER NUMBER	
		3732		

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/018,027	HORVATH ET AL
	Examiner	Art Unit
	Cary E. O'Connor	3732

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 April 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6,8-28 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 24,25 and 32-36 is/are allowed.
- 6) Claim(s) 1-6,8-11,14,16,18-23,26,27,30 and 31 is/are rejected.
- 7) Claim(s) 12,13,15,17 and 28 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Schumacher (DE 29521058). Schumacher shows a device comprising a handle and a removable skeleton form having a hemispherical shape (see figures 5 and 6). As to claim 27, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-6,8-11, 18, 22, 23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski (5,462,781). Zukowski shows a medial membrane comprising a porous structure with a roughened surface. As to claims 4 and 5, note that the membrane may have a width of 5 microns (column 4, line 8), which falls in the range claimed by applicant. As to claim 6, it is held that the membrane is inherently either self adhesive to dentine or may adhere to dentine due to an adhesive coating. As to claims 9 and 10, note that the membrane may be about 5 microns thick (column 4, line 8). As to claim 18, note that the membrane may be made of a non-resorbable material, such as PTFE. As to language in the claims that the membrane may be used for capping a pulp exposure in a dentine cavity, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Without a showing of criticality, the surface area and shape of the membrane are considered to have been obvious design choices dependent on the intended use of the membrane.

Claims 1-6, 18, 22 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (5,348,788). White shows a medial membrane comprising a porous structure 20 with a roughened surface 10. As to claim 3, note column 6, lines 55-58. As to claims 4 and 5, note the abstract. As to claim 6, it is held that the membrane is inherently either self adhesive to dentine or may adhere to dentine due to an adhesive coating. As to claim 18, note that the membrane may be made of silicone rubber which is a non-resorbable material. As to language in the claims that the membrane may be used for capping a pulp exposure in a dentine cavity, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Without a showing of criticality, the surface area and shape of the membrane are considered to have been obvious design choices dependent on the intended use of the membrane.

Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski (5,462,781) in view of Walser. Zukowski does not teach an adhesive coating to adhere the membrane. Walser shows a membrane which has adhesive properties and are carried on a carrier foil 1. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the membrane with

adhesive properties and mount the membranes on a carrier sheet, in view of Walser, so that the membrane may be more securely held on the tissue.

Claims 19-21 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zukowski (5,462,781) in view of Dunn (5,599,552). As to claims 19 and 20, Zukowski does not disclose the use of a resorbable material to form the membrane. Dunn discloses that membranes for use in tissue regeneration made of collagen are well known in the art (column 1, lines 41-43). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the membrane of Zukowski out of collagen, in view of Dunn, so that the membrane would be resorbable and removal of the membrane at a later time would be unnecessary. As to claims 21 and 31, Dunn teaches the use of a growth factor (column 10, lines 33+) and/or an antibacterial substance (column 11, line 21) with a tissue regeneration membrane. It would have been obvious to one of ordinary skill of the art at the time the invention was made to incorporate a growth factor and an antibacterial substance in the membrane of Zukowski, in view of Dunn, in order to promote tissue growth and prevent infection.

Allowable Subject Matter

Claims 24, 25, 32-36 are allowed.

Claims 12, 13, 15, 17 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed April 9, 2004 have been fully considered but they are not persuasive. As to claims 1 , applicant argues that neither Zukowski nor White teach a membrane having a surface area of less than 100 mm². While it is acknowledged that this is true, it is held that, given the uses disclosed by Zukowski or White, it would have been obvious to make the membrane of any size required for the intended use. Thus, if the procedure requires a membrane of a size less than 100 mm², it would have been highly obvious to make it that size. Applicant also argues that the membrane of White does not have a roughened surface but is a porous article. It is held that the protrusions formed between the pores constitute a roughening of the surface. Accordingly, White has, in addition to being porous, a roughened surface. As to claims 26 and 27, applicant argues that the inlay of Schumacher is not fixed to the forceps but is held by them. The examiner asserts that while the inlay is held by the forceps it is "removably fixed" thereto. It is noted that applicant's specification only specifies that the form is fixed to the handle in such a way so that it can be easily attached or removed from the handle (page 12, lines 24-27). The form and handle of Schumacher fit this definition.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 703-308-2701. The examiner can normally be reached on M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-0858. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Cary E. O'Connor
Cary E. O'Connor
Primary Examiner
Art Unit 3732

ceo
July 24, 2004